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09/971,099	10/03/2001	Cynthia C. Bamdad	M01015/70066 TJO	2127

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/971,099

Applicant(s)

BAMDAD, CYNTHIA C.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,5,8-11 and 13-41 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 22-29,40 and 41 is/are allowed.
6) ☒ Claim(s) 2,4,5,8-11,13-21 and 30-39 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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DETAILED ACTION

Amendment Entry and Claim Status

The amendment filed on April 08, 2005 has been acknowledged and entered.

Claims 2, 4, 5, 8-11, 13-41 are pending.

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph in the previous office action is withdrawn herein.

Rejections under 102 and 103 in the previous office action are withdrawn herein.

New Grounds of Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-21, 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite for reciting "the first article being immobilized relative to a signaling entity that is immobilized relative to a binding partner". The binding partner is already linked to the first agent and a nanoparticle being linked to a binding partner. Where else on the binding partner would a signaling entity bind? Where is the signaling entity with respect to the nanoparticle and the first agent?

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Claim 32 fails to further limit claim 9 because in claim 9, the biological agent is already linked to the binding partner. However, claim 32 recites a step of "allowing the biological agent to bind to the binding partner thereof".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 8-11, 30-33, 37, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinsky et al. (US 6,409,925) in view of Oprandy et al. (US 6,096,500).

Gombinsky teaches a system and method for collecting and transferring magnetic particles from a plurality source vessel to a plurality of target vessels. The system comprises a plurality of collecting members each of which can be manipulated independently. Gombinsky further teaches a method for detecting biological entities being fluorescently labeled, wherein the entities are bound to magnetic particles. Each collecting member has a magnetic field providing member, which can be moved in two different positions. When the magnetic field providing member fits the tip of the collecting member, which is placed in a well or vessel that holds the magnetic particle, the magnetic field providing member collects the magnetic particle within said well. When the magnetic field providing member is raised or distanced from the tip, the particles are released into the well or a different well/vessel. In a system composed of a

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plurality of individual collecting members, one collecting member can be at the collecting position while the other collecting member can be at the releasing position. For example, in figure 2, the first collecting member is at a collecting position in which the magnetic particles are at the tip of the collecting member while the second collecting member is at a releasing position. Thus, in accordance with the present invention, the first collecting member in figure 2 magnetically draws/collects the magnetic particles/first article immobilized with a chemical or biological agent to a first position (the tip of the first collecting member) and the second collecting member draws/collects a second article/magnetic particles to a second location and releasing the second article/magnetic particles from the second location while holding the first article/magnetic particles on the first collecting member (see figures 1 and 2; col. 10, line 1-col. 12, line 18). The magnetic particles are capable of specifically binding to the biological entities. The specific binding, is typical carried out by attaching to the magnetic particle one member of a pair-forming group while the other is the biological entity to be detected. The biological entity is equivalent to the "first agent" of the present invention and is linked to a binding partner. The collecting member also comprises of an electromagnet so that when the electromagnet is turned off, the collecting member becomes deactivated and thus releasing the magnetic particles and vice versa. (see figure 3A and col. 7, line 66-col. 8, line 11; lines 61-70). The limitation of "The magnetic particle/first article immobilized to a signaling entity that is immobilized relative to the binding partner" is taught in Gombinsky at col. 8, lines 54-60. A label is reacted with an antibody carrying a label, such antibody is specific to the biological entity being detected. Regarding the first

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and second locations being predetermined areas of a surface, the tip of the collecting member satisfies this requirement because it is a predetermined area on the surface of said collecting member. The biological entity can be DNA sequence and identifying the first agent by identifying the DNA sequence. (see col. 8, lines 28-53).

However, Gombinsky fails to teach the predetermined surface areas comprise an electrode.

Oprandy teaches a multi-labeled probe complex suitable for use in an ECL assay comprising a platform molecule carrying a plurality of electrochemiluminescent labels and may have oligonucleotide probes. The complex is used in combination with magnetic beads which carry a hybridization probe to capture the target nucleic acid and bring them to the electrode surface. The magnet is positioned under the electrode to bring the magnetic beads coated with target molecules. (see col. 3, lines 30-35; col. 4, lines 10-16).

It would have been obvious to one of ordinary skills in the art to use the electrode surface as taught by Oprandy as an alternate solid phase in place of the microtiter plate taught in the method of Gombinsky since Oprandy and Gombinsky both teach capturing/bringing the magnetic particles to the surface of the electrode using a magnet. Electrode can be conveniently used as a solid phase for capturing molecules of interest as well as a measuring means for detecting such molecules without having to transfer the molecules to a detection chamber. An applied magnetic force captures the magnetic beads on the electrode surface stabilizes the target molecule and its attached labeled reporter for maximum detection. (see Oprandy col. 3, lines 45-49).

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Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinsky (US 6,409,925) and Oprandy et al. (US 6,096,500) as applied to claims 4, 5, 8-11, 30-33, 37 and 38 above, and further in view of Ullman et al. (US 6,103,537).

Gombinsky and Oprandy have been discussed above.

However, Gombinsky and Oprandy fails to teach the first chemical or biological agent is a drug candidate.

Ullman teaches method of conducting a capillary electroseparation specific binding assay using magnetic particles and wherein the analytes are drugs, potential drug candidates, metabolites etc. (see col. 5, lines 33-36; col. 6, line 6-col. 7, line 26).

It would have been obvious to one of ordinary skills in the art to detect or collect any target biological or chemical agent such as a drug candidate detect a drug candidate as suggested by Ullman using the combined assay method of Gombinsky and Oprandy since Gombinsky teaches that the biological entities can be any type of molecule, complex of molecules or cells present in biological tissue.

Response to Arguments

Applicant's arguments with respect to claims 2, 4, 5, 8-11, 13-41 have been considered but are moot in view of the new ground(s) of rejection.

Although some claims were indicated allowable in the previous office action, new applicable arts have been found.

Allowable Subject Matter

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Claims 13-21, 34-36, 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior arts fail to teach that the first article comprises of a magnetic bead and a nanoparticle which is linked to the binding partner; said signaling entity is a the nanoparticle which includes an auxiliary signaling entity immobilized thereto; and said signaling entity is a metallocene fastened to the colloid particle.

Claims 22-29 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Pensee T. Do
Patent Examiner
July 7, 2005

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7/11/05